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PhRMA

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May 3, 1999

BY MESSENGER

Office of Information and Regulatory Affairs
Attention: Desk Officer for FDA
Office of Management and Budget
New Executive Office Building
725 17th Street, N.W.
Washington, D.C. 20503

Re: PhRMA Comments to Docket No. 98N-0583
FDA Proposed Rule—Exports:
Notification and Recordkeeping Requirements
(Published April 2, 1999; 64 *Fed. Reg.* 15944)
Initial Comments and Request For Extension of Comment Period to August 16, 1999

Dear OIRA/OMB FDA Desk Officer:

I write on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the above-referenced proposed regulation published by the Food and Drug Administration to implement the notification and recordkeeping provisions of the FDA Export Reform and Enhancement Act of 1996. The *Federal Register* notice announcing the proposed rule requests written comments on the information collection requirements of FDA's proposal by May 3, 1999. PhRMA has prepared an initial set of comments on the information collection burdens of the proposed rule, and I am submitting them to you under cover of this letter. PhRMA also respectfully requests an extension of time until August 16, 1999 in order to submit further detailed comments on the estimated annual reporting and recordkeeping burdens FDA included with the proposed rule.

As you will see from the initial comments submitted with this letter, FDA's proposed rule deviates in major respects from the statute the rule purports to implement, and establishes extensive new paperwork and administrative burdens in direct violation of the letter and spirit of the FDA Export Reform and Enhancement Act of 1996. PhRMA's initial comments highlight the major flaws in FDA's proposed rule, and show why that rule must be withdrawn or substantially revised. An extension of the

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deadline for comments on the information collection requirements of the proposed rule until August 16 is necessary for PhRMA to prepare, in addition to the comments it has already prepared, a more extensive assessment and critique of FDA's analysis of the proposed rule under the Paperwork Reduction Act of 1995. Preliminary review shows that FDA's estimates are grossly inaccurate and unrealistic; additional time is necessary to allow a more thorough assessment of this flawed proposal.

Thank you for your consideration of our comments and our request for an extension of time in which to submit additional comments. If you have any questions, please do not hesitate to contact me.

Sincerely,

Matthew B. Van Hook

Enclosure

cc: Philip L. Chao, Office of Policy (HF-23), FDA
Dockets Management Branch (HFA-305), FDA

May 3, 1999

COMMENTS OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

ON

INFORMATION COLLECTION REQUIREMENTS FOR FDA'S PROPOSED RULE ON EXPORT NOTIFICATION AND RECORDKEEPING REQUIREMENTS

DOCKET NO. 98N-0583

SUBMITTED TO THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA companies are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing over $24 billion a year in discovering and developing new treatments, PhRMA companies are leading the way in the search for cures. As pioneers in the discovery and development of new medicines, PhRMA companies are involved in activities with a truly global reach. In particular, PhRMA companies export drugs and biologics to countries around the world, and, therefore, have a keen interest in the rules that apply to exports.

Historically, the United States has had one of the most restrictive drug export policies of any country in the world.[1] In 1986, Congress enacted the Drug Export Amendments Act (Pub. L. No. 99-960) (the "1986 Amendments") and created a three-

[1] *See* S. Rep. No. 225, 99th Cong., 1st Ses. 5-6 (1985).

track system requiring three different levels of approval from FDA for exports, depending on the drug being exported and the regulatory environment in the receiving country. The 1986 Amendments proved inadequate, because they limited exports of unapproved drugs to 21 countries. In addition, the requirement of seeking FDA approval prior to export proved overly burdensome.

Then, in 1996, Congress sought to modernize and liberalize the still restrictive export policies by enacting the FDA Export Reform and Enhancement Act of 1996 (Pub. L. No. 104-132) (the "1996 Amendments"). The 1996 Amendments amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to streamline export requirements and authorize the export of products not approved in the United States under the circumstances set forth in the new statutory scheme.

PhRMA submits these comments to the Office of Management and Budget because FDA has proposed to implement the export notification and recordkeeping requirements of the 1996 Amendments[2] in a manner that violates the letter and spirit of the 1996 Amendments. Put simply, FDA proposes to create burdensome new administrative requirements of the very type Congress sought to eliminate. These improper and unauthorized paperwork burdens, if allowed to stand, will impede the export of products. FDA must revise its current thinking and either withdraw or

[2] *See* 64 Fed. Reg. 15944 (April 2, 1999).

substantially revise its proposed rule in order to administer the new law in a manner that is faithful to the statute and Congress's intent. The particular respects in which FDA's proposed rule violates the 1996 Amendments and imposes improper information collection and paperwork burdens are detailed below.

I. Proposed 21 C.F.R. § 1.101(b) -- Recordkeeping Requirements

All products exported under the 1996 Amendments must comply with the general requirements of Section 801(e)(1) of the FDCA. Those general statutory requirements are straightforward. To be exported, a drug product must (1) accord to the specifications of the foreign purchaser; (2) not be in conflict with the laws of the country to which it is intended for export; (3) be labeled on the outside of the shipping package that it is intended for export; and (4) not be sold or offered for sale in domestic commerce. If a company complies with these requirements, the product is not adulterated or misbranded under the FDCA.

The elaborate records that FDA is proposing that a company maintain to demonstrate its compliance with these provisions are not required, and are not authorized, by the statute. Indeed, FDA appears to be contemplating records beyond those traditionally required under Section 801(e). FDA's proposed requirements represent the very type of burdensome bureaucratic procedures that Congress intended to eliminate in reforming the export requirements. Congress quite explicitly established only minimal recordkeeping requirements for exporters. *See, e.g.*, FDCA

§ 802(g). Companies simply are not required to keep the kind of records that FDA has suggested, so long as they comply with the substance of the statute in their actual export activities. Were companies expected to keep such records, the practical effect would be to inhibit exports that are explicitly authorized under the statute.[3]

In particular, under the statute, exporters are not required to maintain detailed records of the product specifications requested by the foreign purchaser related to the product's dosage strength, dosage form, purity, quality, operating parameters, composition, etc. Proposed 1.101(b)(1). Neither are they required to keep records about the details of the product's manufacture related to sterilization processes, compliance with manufacturing standards, etc. Proposed 1.101(b)(1). Independent of the 1996 Amendments, manufacturers are required to maintain certain records as part of their current good manufacturing practices ("cGMPs"). These records should suffice under the 1996 Amendments as well, and the 1996 Amendments do not authorize FDA to impose additional record-keeping requirements.

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[3] Situations may arise in which companies will have to produce records of their bona fide compliance with Section 801(e)(1). For example, in the *Kanasco* case, the United States Court of Appeals for the Fourth Circuit held that a company cannot defend an FDA seizure by making an unsupported post hoc assertion that otherwise adulterated products were intended for export. *United States v. Kanasco, Ltd.*, 123 F.3d 209 (4th Cir. 1997). However, neither the 1996 Amendments nor the *Kanasco* case prescribe precisely how a manufacturer must establish its intent to export products. It would be reasonable to expect that companies would maintain records establishing their bona fide export activities, but the precise form of those records rests in the first instance within a company's discretion. FDA's proposed rule reflects a much different approach that outlines very detailed recordkeeping requirements not authorized by the statute.

The requirement that companies obtain a letter, or any other documentary proof, from a foreign government agency, department or body stating that the product has marketing approval from the foreign government and does not conflict with that country's laws is also outside the scope of FDA's authority. Proposed 1.101(b)(2). As demonstrated by FDA's "Part 312 program," obtaining confirmatory letters from foreign officials constitutes a significant administrative burden and can cause substantial delay. Further, in some circumstances there will be no express marketing approval from the foreign health authority (*e.g.*, where the foreign authority allows an active ingredient to be reworked to bring it into specifications without any formal approval or special documentation). Thus, Congress quite reasonably did not establish a requirement that an exporter obtain a letter or other documentary proof from foreign officials. If the product is in accord with the laws of the destination country, the export is permitted under the statute.

There are numerous ways in which a company can ensure that its exports meet the statutory requirement. For example, nowhere did Congress assert or even imply that advice of counsel or other due diligence by a company official would be inadequate to document the exported product's compliance with the destination country's laws, and it is unclear why FDA takes this position now. FDA's proposed establishment of this new requirement, in violation of the statute, creates both a significant administrative and paperwork burden, and risks preventing outright the export of certain products.

Similarly, the statute does not require that firms maintain special records to establish that the exported product is only sold or offered for sale abroad. Proposed 1.101(b)(4). Even if they were required to maintain such records, it remains unclear what FDA means when it states that firms should maintain records concerning "similar products," and what bearing such records would have on whether the exported product is sold in domestic commerce.

Finally, FDA's proposed requirement that records be retained for 5 years (proposed 1.101(b)) is excessive. No particular retention period is required by statute, and companies should remain free to follow standard document retention policies such as the GMP requirement that distribution records be retained for one year after the product's expiration date (21 C.F.R. §211.180).

II. Proposed 21 C.F.R. § 1.101(d) -- Notification Requirements

A. General Requirements

The 1996 Amendments require that, for exports of a drug to a listed country under Section 802(b)(1), an exporter provide a "*simple* notification" to FDA identifying the drug when the export "first begins." FDCA § 802(g) (emphasis added). FDA proposes to mandate that exporters identify the country that is to receive the exported product as well (proposed 1.101(d)(1)(iv)), although such a requirement clearly does not exist under the statute. Indeed, FDA itself concedes that "for exports to listed countries under section 802(b)(1) of the act, section 802(g) of the act requires the

notification to identify only the drug, biologic, or device being exported and does not expressly require the notification to identify the country to which the drug, biologic, or device is being exported." 64 Fed. Reg. at 15945-46.

FDA attempts to justify this proposed new requirement, notwithstanding the lack of supporting statutory authority, by claiming that such additional information is necessary to facilitate the agency's own enforcement responsibilities. However, the statute is unambiguous. Moreover, FDA's proposal significantly complicates what Congress intended to be a simple notification process, for companies would need to send multiple notices as exports continue to additional listed countries.

B. Exports in Anticipation of Market Authorization

The 1996 Amendments allow a company to export an unapproved drug to any listed country for additional processing, packing, labeling, or similar operations in order to "fill the pipeline" prior to marketing approval, as long as the shipment complies with the law of the listed country. FDCA § 802(d). For products that are exported under Section 802(d), no notification or reporting requirements exist. Yet FDA's proposed rule provides that firms notify FDA when they export products under this section. FDA itself admits that "[a] literal interpretation of section 802(g) of the act would not require an exporter to notify FDA when it shipped a product to a listed country in anticipation of market authorization." 64 Fed. Reg. at 15945. FDA cannot justify this requirement by declaring summarily that it would be more "simple and efficient" for exporters to notify

FDA when they export a product in anticipation of marketing authorization. The statute is clear, and it does not permit FDA to establish yet another new administrative and paperwork burden, as it has proposed.

III. Recordkeeping Requirements for Products Subject to Section 802(g) -- Proposed 21 C.F.R. § 1.101(e)

The 1996 Amendments require that an exporter must "maintain records of all drugs . . . exported and the countries to which they were exported." FDCA § 802(g). FDA improperly proposed the establishment of additional recordkeeping burdens by providing that exporters maintain records also showing exports by lot or control number and by consignee's name and address. As noted above regarding other new recordkeeping requirements FDA is proposing to create, manufacturers are required to maintain certain records as part of their cGMP obligations; however, the additional detail FDA is proposing here is neither required nor authorized under the 1996 Amendments. As also explained above, FDA's proposed requirement that records be retained for 5 years (proposed 1.101(e)(2)) is excessive. No particular retention period is required by statute, and companies should be free to follow standard document retention policies such as the GMP requirement that distribution records be retained for one year after the product's expiration date (21 C.F.R. §211.180).

IV. FDA's Estimated Annual Reporting and Recordkeeping Burdens

On its face, FDA's analysis of the estimated annual reporting and recordkeeping burden of its proposed rule is grossly inaccurate and unrealistic. However, PhRMA would prefer to have additional time to gather and analyze data from its member companies in order to provide additional perspective on the administrative burdens of FDA's proposed rule. Accordingly, PhRMA requests an extension of the deadline for filing comments with OMB until August 16, 1996 in order to submit supplemental comments on the paperwork burdens associated with FDA's proposed rule. PhRMA respectfully submits that this extension is justified in light of the importance of FDA's proposed regulation, the magnitude of the unauthorized administrative burdens associated with FDA's proposal, and the time necessary to gather and assess detailed data in support of supplemental comments.

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The 1996 Amendments modernize and streamline the United States' chronically anachronistic and restrictive export laws. FDA's proposed rule re-establishes the very bureaucratic and prohibitive requirements that Congress expressly intended to eliminate. FDA's proposed rule must be withdrawn or substantially revised in order to eliminate this backsliding and bring FDA's implementation in line with the letter and the spirit of the 1996 Amendments.